



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-2826]

Allergan Sales LLC., et. al.; Withdrawal of Approval of 10 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the *Federal Register* on November 21, 2022. The document announced the withdrawal of approval (as of December 21, 2022) of 10 abbreviated new drug applications (ANDAs) from multiple applicants. The document indicated that FDA was withdrawing approval of the following ANDAs after receiving withdrawal requests from Sunstar Americas, Inc., 301 East Central Rd., Schaumburg, IL 60195: ANDA 076434, Chlorhexidine Gluconate Solution, 0.12%; Sofgen Pharmaceuticals, LLC, 21500 Biscayne Blvd., Suite 600, Aventura, FL 33180: ANDA 201832, Nimodipine Capsules, 30 milligrams (mg); and Indicus Pharma, LLC, 2530 Meridian Parkway, Durham, NC 27713: ANDA 203419, Donepezil HCl Tablets, 23 mg. Before FDA withdrew the approval of these ANDAs, Sunstar Americas, Inc., Sofgen Pharmaceuticals, LLC, and Indicus Pharma, LLC informed FDA that they did not want the approval of the ANDAs withdrawn. Because Sunstar Americas, Inc. timely requested that approval of ANDA 076434 not be withdrawn, Sofgen Pharmaceuticals, LLC timely requested that the approval of ANDA 201832 not be withdrawn, and Indicus Pharma, LLC timely requested that the approval of ANDA 203419 not be withdrawn, the approvals are still in effect.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993-0002, 240-402-6980, Martha.Nguyen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

In the *Federal Register* of Monday, November 21, 2022 (87 FR 223), in FR Doc. 2022-25315, the following correction is made:

On page 70835, in the table, the entries for ANDAs 076434, 201832, and 203419 are removed.

Dated: January 30, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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